K010488

APR - 9 2001

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SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The ATAC PAK AST Reagent Kit and the ATAC 8000 Random Access Chemistry System are intended for use as a system for the quantitative determination of aspartate aminotransferase in serum and plasma. AST results are used in the diagnosis and treatment of certain types of liver and heart disease. The ATAC PAK AST Reagent determines aspartate aminotransferase through the enzymatic oxidation of NADH. The resulting rate of decrease in absorbance at approximately 340 nm is proportional to the aspartate aminotransferase activity in the sample. The ATAC PAK AST Reagent Kit is substantially equivalent to the AST Reagent Kit, product no. 704038, which was originally marketed by Boehringer Mannheim and is now marketed by Roche Diagnostics Systems of Branchburg, NJ.

The effectiveness of ATAC PAK AST Reagent Kit and the ATAC 8000 Random Access Chemistry System is shown by the following studies.

The recovery of aspartate aminotransferase using the ATAC PAK AST Reagent is linear from 5 to 650 U/L in the primary usable range and from 550 to 2,600 U/L in the hyperactive dilution range as shown by the recovery of linearity standards which span the respective ranges. For both ranges, the coefficient of determination (r^2) approaches 1.0, and the standard error of regression ($s_{y.x}$) is less than 1.5% of the upper limit of the claimed range.

Regression statistics, which compare standard recoveries to standard dilution factors in both ranges, are shown below.

Primary Usable Range (from 5 to 650 U/L)
ATAC Results = 1.5 + 1.005 x Standard Factors
range = 3 - 780 U/L, $r^2 = 1.000$, $s_{y.x} = 5.6$ U/L, df = 49

Hyperactive Usable Range (from 550 to 2,600 U/L)
ATAC Results = 3.4 + 1.007 x Standard Factors
range = 430 - 2,680 U/L, $r^2 = 0.998$, $s_{y.x} = 35.1$ U/L, df = 60

Precision, using both the normal sample volume and the reduced sample volume in the hyperactive dilution range, is demonstrated by the replicate assay of commercially available serum controls. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

Precision of AST Recoveries in U/L

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	54	24	1.2	5.2%	1.4	6.1%
Serum 2	54	185	2.5	1.4%	3.5	1.9%
Serum 3	54	337	3.6	1.1%	6.1	1.8%

Precision of AST Recoveries in U/L using Hyperactive Dilution

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	54	764	11	1.4%	12	1.6%
Serum 2	53	1,477	21	1.4%	24	1.6%
Serum 3	54	2,157	29	1.3%	35	1.6%

Mixed serum and plasma specimens, collected from adult patients, were assayed for aspartate aminotransferase at 37°C using the ATAC 8000 Random Access Chemistry System and another commercially available method. Results were compared by least squares linear regression and the following statistics were obtained.

ATAC 8000 = 3.6 U/L + 0.915 x Competitive Reagent
r = 0.999 n = 199 range = 7 - 425 U/L

The 30 day on board reagent stability claim is documented through the assay of serum controls over the claimed period. In all cases, the total imprecision estimates of aspartate aminotransferase recoveries over the test period are less than 3 U/L or 3% for both the primary usable range and the extended hyperactive dilution range.

Wynn Stocking 3/26/01

Wynn Stocking
Manager of Regulatory Affairs
Elan Diagnostics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR - 9 2001

Mr. Wynn Stocking
Manager, Regulatory Affairs
Elan Diagnostics
231 N. Puente Street
Brea CA 92821

Re: 510(k) NUMBER: K010488
Trade/Device Name: ATAC PAK AST Reagent
Regulation Number: 862.1100
Regulatory Class: II
Product Code: CIT
Dated: February 16, 2001
Received: February 20, 2001

Dear Mr. Stocking:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K010488

Device Name: ATAC PAK AST Reagent

Indications For Use:

The ATAC PAK AST Reagent Kit and the ATAC 8000 Random Access Chemistry System are intended for use as a system for the quantitative determination of aspartate aminotransferase (AST) in serum and plasma. Aspartate aminotransferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

Respectfully,

Wynn Stocking

Wynn Stocking
Regulatory Affairs Manager
Elan Diagnostics

16 February, 2001

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010488

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)